



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

July 16, 2004

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

Memorandum

SUBJECT: CASAC Ambient Air Monitoring and Methods (AAMM) Subcommittee "Coarse Particulate Matter (PMc) Methods Evaluation" Meeting Memorandum of Determinations

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This memorandum addresses the set of determinations that were necessary for forming the Clean Air Scientific Advisory Committee (CASAC) Ambient Air Monitoring and Methods (AAMM) Subcommittee (Subcommittee) that will be conducting a consultation on "Coarse Particulate Matter (PMc) Methods Evaluation." This memo provides background information on the subject CASAC activity, and addresses the following determinations:

- (1) The type of review body that will be used to conduct the review, the name of the Subcommittee, and identification of the Subcommittee Chair;
- (2) The charge developed for the Subcommittee;
- (3) The types of expertise needed to address the charge;
- (4) Financial conflict of interest considerations, including identification of parties who are potentially interested in or may be affected by the topic to be reviewed;
- (5) How regulations concerning "appearance of a lack of impartiality," pursuant to 5 C.F.R. § 2635.502 apply to members of the Subcommittee; and
- (6) How individuals were selected for the Subcommittee.

DETERMINATIONS:

- (1) The type of review body that will be used to conduct the review, the name of the Subcommittee, and identification of the Subcommittee Chair.

EPA's Office of Air Quality Planning and Standards (OAQPS) requested that the CASAC provide advice on the following two projects in fiscal year (FY) 2004: "PMc Methods Evaluation," and "Ambient Air Monitoring Strategy Implementation Plan." Accordingly, the SAB Staff Office held an administrative teleconference with the seven members of the chartered (statutory) CASAC to discuss options for forming CASAC subcommittee(s) to conduct these OAQPS projects. The CASAC recommended the formation of a subcommittee provide advice related to ambient air monitoring and methods.

Per the discussion in the Background section above, the two FY 2004 OAQPS projects — *i.e.*, "Coarse Particulate Matter (PMc) Methods Evaluation," and "Ambient Air Monitoring Strategy Implementation Plan" — will be conducted by a new, standing subcommittee of the CASAC named the CASAC AAMM Subcommittee. This Subcommittee will be chaired by the Chair of the CASAC, currently Dr. Philip Hopke.

- (2) The charge developed for the Subcommittee.

The SAB Staff Office, OAQPS staff, and the Chair of the Panel negotiated the following charge questions on which Agency would ask the CASAC AAMM Subcommittee to focus during its consultation on "Coarse Particulate Matter (PMc) Methods Evaluation":

1. What are the strengths and weaknesses of each method tested in the ORD study for purposes of using it as a reference method, a measurement principle, and as a method that would provide the basis for approval of candidate reference and equivalent methods?
2. What are the strengths and weaknesses of each method tested to meet multiple monitoring objectives such as comparison to potential PMc standards, public reporting, trends, chemical speciation, and characterization of short-term episodes and diurnal variation?
3. For the PMc DQOs, is the process the Agency took to develop the estimates of uncertainty appropriate? Are there factors the Agency has included that should not be considered or are there other inputs that should be included?"

- (3) The types of expertise needed to address the charge.

Per the solicitation for nominees to form the CASAC AAMM Subcommittee published in the *Federal Register* (69 FR 19180) on April 12, 2004, national and international experts were sought in one or more of the following five areas:

(a) Atmospheric sciences and air quality simulation modeling. Areas of expertise include the development and application of regional and larger-scale air quality dispersion models to predict atmospheric concentrations of ozone, particulate matter and other air pollutants, with emphasis placed on the application of such systems to developing emission control strategies in support of national-level programs or State Implementation Plans (SIPs).

Related areas of expertise include individuals with expertise in mechanisms of chemical interactions, source-receptor modeling, observational-based models and related data analysis expertise and conceptual model development.

(b) Human health effects and exposure assessment. Areas of expertise include utilizing ambient monitoring data in epidemiology, toxicology, and related disciplines that examine the causative relationships between air pollution and adverse health effects in indoor and outdoor environments.

(c) Air quality measurement science. Areas of expertise include measurement of criteria and hazardous air pollutants in particulate matter and gaseous samples with an understanding of routine monitoring conducted by most State and local agencies, an interest in and an understanding of integrating advanced methodologies into monitoring networks and transferring new technological advances to routine use by government air quality agencies.

(d) Ecological risk assessment. Areas of expertise include the assessment of ecosystem exposure to criteria and hazardous air pollutants and the use of such data in ecosystem risk assessment.

(e) State, local agency or Tribal experience. Areas of expertise include experience working in a State, local agency or Tribal organization familiar with the practical logistics of conducting air monitoring operations, as well as in air monitoring network design.

(4) Financial conflict of interest considerations, including identification of parties who are potentially interested in or may be affected by the topic to be reviewed.

(a) Identification of parties who are potentially interested in or may be affected by the topic to be reviewed: The principal interested and affected parties for this project are: (1) research universities; (2) State and local air program (or air pollution control) agencies; and (3) EPA. In addition, industry-related parties involved in the manufacture, marketing, sale, installation and maintenance of various ambient air monitoring technologies, especially PM_{2.5} and PM₁₀ FRM samplers and associated equipment — referred-to collectively herein as “industry/manufacturers” — would also have an interest in this topic.

(b) Conflict of interest considerations: For Financial Conflict of Interest (COI) issues, the basic 18 U.S.C. § 208 provision states that: “An employee is prohibited from participating *personally and substantially* in an official capacity in any *particular matter* in which he, to his knowledge, or any person whose interests are imputed to him under this statute has a *financial interest*, if the particular matter will have a direct and predictable effect on that interest [emphasis added].” For a conflict of interest to be present, all elements in the above provision must be present. If an element is missing the issue does not involve a formal conflict of interest; however, the general provisions in the appearance of impartiality guidelines must still apply and need to be considered.

(i) Does the charge involve a particular matter? A “particular matter” refers to matters that “...will involve deliberation, decision, or action that is focused upon the interests of specific people, or a discrete and identifiable class of people.” It does not refer to “...consideration or adoption of broad policy options directed to the interests of a large and

diverse group of people.” [5 C.F.R. § 2640.103 (a)(1)]. A particular matter of general applicability means a particular matter that is focused on the interests of a discrete and identifiable class of persons, but does not involve specific parties. [5 C.F.R. § 2640.102 (m)].

The CASAC AAMM Subcommittee’s activity in addressing the charge for the consultation on “PMc Methods Evaluation” qualifies as a *particular matter of general applicability* because the resulting advice will be part of a deliberation, and under certain circumstances the advice could involve the interests of a discrete and identifiable class of people but does not involve specific parties. That group of people constitutes those who are associated or involved with: (1) research universities; (2) State and local air program (or air pollution control) agencies; and (3) EPA.

The Special Government Employees (SGEs) who are to serve on the CASAC AAMM Subcommittee for this “PMc Methods Evaluation” consultative meeting are part of a group of people who could represent organizations that in the future might be regulated by EPA or seek grant or contract funding for projects in research areas identified by the Subcommittee. *Thus, the matter does involve deliberation that focuses upon the interests of a distinct and identifiable group of people, that is, the community that may be subject to EPA regulations or receive grant or contract funding from the Agency related to the topics under review or consultation by the Subcommittee.*

(ii) Will there be personal and substantial participation on the part of Subcommittee members? Participating personally means direct participation in this consultation. Participating substantially refers to involvement that is of significance to the matter under consideration. [5 C.F.R. § 2640.103(a)(2)]. For this review, the SAB Staff Office has determined that *CASAC AAMM Subcommittee members will be participating personally in the matter*. Subcommittee members will be providing OAQPS with advice and recommendations that is expected to include an assessment of the relative strengths and weaknesses of each coarse particulate matter method tested to meet multiple ambient air monitoring objectives that is intended to help inform the Agency’s possible selection of PMc measurement methods. *Therefore, participation in this consultation will also be substantial.*

(iii) Will there be a direct and predictable effect on CASAC AAMM Subcommittee members’ financial interest? A direct effect on a participant’s financial interest exists if “...a close causal link exists between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest. ...A particular matter does not have a direct effect ...if the chain of causation is attenuated or is contingent upon the occurrence of events that are speculative or that are independent of, and unrelated to, the matter. A particular matter that has an effect on a financial interest only as a consequence of its effects on the general economy is not considered to have a direct effect.” [5 C.F.R. § 2640.103(a)(i)] A predictable effect exists if, “...there is an actual, as opposed to a speculative, possibility that the matter will affect the financial interest.” [5 C.F.R. § 2640.103(a)(ii)]

Each CASAC AAMM Subcommittee member could conceivably have financial links to the Agency in the form of existing or pending grants, cooperative agreements, contracts, or other funding. Furthermore, each of these individuals could submit proposals for such grants, cooperative agreements, contracts or other funding in the future.

In determining whether a member's or candidates' participation has a direct and predictable effect on their financial interest, the SAB Staff Office has evaluated the process for awarding grants and whether it could directly tie a person's actions in this review to financial gain. In evaluating this factor, the requirement is that a person's actions in participating in the matter must have a "close causal link" to their financial interest. Further, the link must be predictable, that is actual and not "speculative." In the case of members of the CASAC AAMM Subcommittee, the "chain of causation" is attenuated and contingent upon the occurrence of events that are speculative. Thus, while Subcommittee members may, in the course of this consultation, provide OAQPS with advice and recommendations that is expected to include an assessment of the relative strengths and weaknesses of each PMc method tested to meet multiple ambient air monitoring objectives (which should, in turn, help inform EPA's possible selection of PMc measurement methods), provision of this advice would have no direct correlation with an individual Subcommittee member's receipt of current or future grants, cooperative agreements, contracts, or other funding from the Agency.

Moreover, selection of grant recipients follows a complex two-stage process in which independent reviewers judge the scientific quality of a proposal and then Agency representatives judge the relevance of the proposal to answering major scientific questions within the subject area. Thus, actual selection of grant recipients is mediated by a chain of events that attenuates any direct linking of a grant to a panel member's participation in this or subsequent CASAC AAMM Subcommittee reviews, consultations or other activities. Therefore, any effects from participating in this review would not be direct, nor would they be predictable. Accordingly, no conflict-of-interest as defined by 18 U.S.C. § 208 exists in association with grant holding by members of the CASAC AAMM Subcommittee.

Furthermore, because the procedures for awarding grants, cooperative agreements, contracts, or other funding differ, each specific situation has been evaluated to determine if a direct and predictable effect exists between a Subcommittee member's participation and their financial interest. Finally, matters in which CASAC AAMM Subcommittee members have grants, cooperative agreements, contracts or other funding from the Agency that are for work that fits conceptually or specifically within the expected work of this Subcommittee have been evaluated under the requirements for considering "appearance of impartiality" under 5 C.F.R. § 2635.502, as discussed below in Section (5).

As a result of a review of the Agency's Confidential Financial Disclosure Form (EPA Form 3110-48) provided by each prospective CASAC AAMM Subcommittee member, the SAB Ethics and FACA Policy Officer, in consultation with the EPA Alternate Agency Ethics Official, has determined that there is no financial conflict-of-interest presented for the selectees for the CASAC AAMM Subcommittee. In addition, the CASAC AAMM Subcommittee's advice on the particular matter under review will not have a direct effect on the financial interest of CASAC AAMM Subcommittee members.

- (5) How regulations concerning “appearance of a lack of impartiality,” pursuant to 5 C.F.R. § 2635.502, apply to members of the Subcommittee.

The Code of Federal Regulations at 5 C.F.R. § 2635.502(a) states that: “Where an employee knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of his household, or knows that a person with whom he has a covered relationship is or represents a party to such matter, and where the person determines that the circumstances would cause a reasonable party to such matter, and where the person determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his impartiality in the matter, the employee should not participate in the matter unless he has informed the agency designee of the appearance problem and received authorization from the agency designee.” Further, § 2635.502(a)(2) states that, “An employee who is concerned that circumstances other than those specifically described in this section would raise a question regarding his impartiality should use the process described in this section to determine whether he should or should not participate in a particular matter.”

As noted above in Section (4)(b)(ii), the CASAC AAMM Subcommittee’s activity in addressing the charge for the consultation on “Coarse Particulate Matter Methods Evaluation” qualifies as a *particular matter of general applicability* because the resulting advice will be part of a deliberation, and under certain circumstances the advice could involve the interests of a discrete and identifiable class of people but does not involve specific parties. However, as also noted above in Section (4)(b)(ii), the chain of events for a grant is attenuated by certain factors that do not constitute a conflict of interest; thus, the criterion for “appearance of impartiality” at 5 C.F.R. § 2635.502(a) is not met. EPA grant, cooperative agreement, contracts or other funding may present a different situation, and each Subcommittee member was evaluated to determine whether his or her financial interest in existing grants, cooperative agreements, contracts or other funding constitutes an “appearance of impartiality.”

Even though circumstances for some specific candidates for the Subcommittee may raise neither formal conflict-of-interest nor formal appearance concerns, each candidate was evaluated against the five 5 C.F.R. § 2635(a)(2) general requirements to ensure that lack of an appearance of impartiality issues do not preclude their participation. Information used in this evaluation has come from Subcommittee members’ EPA 3110-48 forms and other staff research. For those CASAC AAMM Subcommittee members who hold grants, cooperative agreements, contracts or other funding, or who are involved with organizations subject to regulation by EPA, the SAB Staff Office has determined whether the “reasonable person” criterion is met in the following manner:

(a) Those who are employed by the EPA regulated community were considered to meet this criterion; and

(b) Those who have pending grants, cooperative agreements, contracts or other funding could be directly received from EPA were considered to have met the criterion.

To further ascertain whether there was any potentially disqualifying involvement with the topic of the CASAC AAMM Subcommittee’s consultative meeting which might indicate the

appearance of a lack of impartiality, the following five (5) questions were posed to all candidates for the CASAC AAMM Subcommittee with respect to the “PMc Methods Evaluation” project:

(a) Do you know of any reason that you might be unable to provide impartial advice on the matter to come before the Subcommittee or any reason that your impartiality in the matter might be questioned?

(b) Have you had any previous involvement with the review document(s) under consideration, including authorship, collaboration with the authors, or previous peer review functions? If so, please identify and describe that involvement.

(c) Have you served on previous advisory panels, committees or subcommittees that have addressed the topic under consideration? If so please identify those activities.

(d) Have you made any public statements (written or oral) on the issue? If so, please identify those statements.

(e) Have you made any public statements that would indicate to an observer that you have taken a position on the issue under consideration? If so, please identify those statements.

As a result of a review of the EPA Form 3110-48 and the responses to the above (5) questions provided by each prospective CASAC AAMM Subcommittee member, the CASAC DFO, the SAB Ethics and FACA Policy Officer, in consultation with the SAB's Deputy Ethics Official has determined that there is no appearance of a lack of impartiality on the part of the selectees for the CASAC AAMM Subcommittee.

(6) How individuals were selected for the Subcommittee.

A solicitation for nominees to form the CASAC AAMM Subcommittee was published in the *Federal Register* (69 FR 19180) on April 12, 2004. A total of 28 individuals responded to the *Federal Register* solicitation (i.e., the “Widecast”) by submitting nominations in electronic format through the “Form for Nominating Individuals to Panels of the EPA Science Advisory Board provided” on the SAB Web site (<http://www.epa.gov/sab>). Each electronic nomination (or self-nomination) included their nominator’s (or their own) assessment of relevant expertise for this Subcommittee from the following categories listed in the *Federal Register* notice: (a) atmospheric sciences and air quality simulation modeling; (b) human health effects and exposure assessment; (c) air quality measurement science; (d) ecological risk assessment; and (e) State, local agency or Tribal experience.

From this list of nominees on the Widecast, the SAB Staff Office selected a “Short List” of 25 candidates for the CASAC AAMM Subcommittee. Nominees were selected for the Short List on the basis of whether they possessed the relevant scientific and/or technical expertise, knowledge, and experience to serve on the Subcommittee, pursuant to the *Federal Register* notice.

The names of the CASAC AAMM Subcommittee Short List candidates, along with their biographical sketches (“biosketches”), was posted May 19, 2004 on the SAB Web site at URL: http://www.epa.gov/sab/panels/casac_aamm_subcom.html for a 21-day period to solicit any comments from members of the public with respect to relevant information that the SAB Staff

Office should consider in the final selection of the Subcommittee. During this three-week period, only one comment was received from the public concerning a candidate for the CASAC AAMM Subcommittee from the Missouri Department of Natural Resources, Air Pollution Control Program.

The SAB Staff Office Director — in consultation with the CASAC Chair and EPA — makes the final decision about who serves on the CASAC AAMM Subcommittee during the “Panel Selection” phase. For the EPA SAB Staff Office, a balanced subcommittee or review panel is characterized by inclusion of candidates who possess the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors, can be influenced by work history and affiliation), and the collective breadth of experience to adequately address the charge. Public responses to the Short List candidates will be considered in the selection of the Subcommittee, along with information provided by candidates and information independently-gathered by the SAB Staff Office on the background of each candidate (*e.g.*, financial disclosure information and computer searches to evaluate a nominee’s prior involvement with the topic under review). Specific criteria to be used in evaluating an individual Subcommittee member include: (a) scientific and/or technical expertise, knowledge, and experience (primary factors); (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) scientific credibility and impartiality; and (e) skills working in advisory committees, subcommittees and review panels. Selectees for the CASAC AAMM Subcommittee possess backgrounds that include experience with academia, States, industry, and consultant groups.

Accordingly, on the basis of the above-specified criteria, the following seventeen (17) experts were selected as members of the CASAC AAMM Subcommittee:

1. Mr. George Allen, Northeast States for Coordinated Air Use Management (MA)
2. Dr. Judith Chow, Desert Research Institute (NV)
3. Mr. Bart Croes, California Air Resources Board (CA)
4. Dr. Kenneth Demerjian, SUNY Albany (NY)
5. Dr. Delbert J. Eatough, Brigham Young University (UT)
6. Mr. Eric Edgerton, Atmospheric Research & Analysis (NC)
7. Mr. Henry D. (Dirk) Felton, New York State Department of Environmental Conservation (NY)
8. Dr. Rudolf Husar, Washington University, St. Louis (MO)
9. Dr. Kazuhiko Ito, NYU School of Medicine (NY)
10. Dr. Donna Kenski, Lake Michigan Air Directors Consortium (IL)
11. Dr. Thomas Lumley, University of Washington (WA)
12. Dr. Peter McMurry, University of Minnesota (MN)
13. Dr. Kim Prather, University of California, San Diego (CA)
14. Dr. Armistead (Ted) Russell, Georgia Institute of Technology (GA)
15. Dr. Jay Turner, Washington University, St. Louis (MO)
16. Dr. Warren White, University of California, Davis (CA)
17. Dr. Yousheng Zeng, Providence Engineering & Environmental Group LLC (LA)

These members will supplement the following three (3) members of the statutory (chartered) Clean Air Scientific Advisory Committee who will also serve as members of the CASAC AAMM Subcommittee:

1. Dr. Philip Hopke, Clarkson University (NY) – Chair
2. Dr. Ellis Cowling, North Carolina State University (NC)
3. Mr. Richard Poirot, Department of Environmental Conservation, Vermont Agency of Natural Resources (VT)

Concurred:

/Signed/

July 16, 2004

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Date